

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Mariagrazia
Pizza, Maria Rita Fontana, Valentina
Giannelli and Rino Rappuoli

COPY

Serial No.: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Filing Date: March 28, 2001

Examiner: Not Yet Assigned

For: IMMUNOGENIC DETOXIFIED MUTANTS OF CHOLERA TOXIN

EXPRESS MAIL LABEL NO: EL650 273 365US
DATE OF DEPOSIT: March 28, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

DECLARATION OF DOREEN YATKO TRUJILLO

1. I am an attorney admitted to practice law in the States of Texas and Pennsylvania, and am registered before the United States Patent and Trademark Office, Registration No. 35,719.
2. I am an attorney of record in the parent of present patent application.
3. The "Preliminary Amendment" submitted herewith includes an amendment to incorporate a statement, and figure to which the statement refers, from WO 93/13202 incorporated by reference thereto in the present application as filed.
4. The statement is presumed to be essential, as is the figure to which it refers.
5. On page 5, line 33, through page 6, line 6, of the above-identified application as filed, the disclosure of immunogenic detoxified proteins in WO 93/13202 comprising mutations at one or more select amino acid positions in the amino acid sequence of subunit A of cholera toxin (CT-A) and subunit A of heat labile toxin A (LT-A) is described.

6. On page 7, lines 1-3, of WO 93/13202, it is reported that the amino acid positions referred to therein correspond to positions in CT-A. Figure 1 is referenced. Figure 1 of WO 93/13202 includes a comparison of CT-A and various LT-A sequences.

7. The description of Figure 1 on page 11, lines 20-27, of WO 93/13202, indicates that the symbol “.” denotes an absent amino acid and the symbol “-” indicates an amino acid in the sequences of LT1 and LT2 that is identical to the corresponding amino acid in CT.

8. The amendatory material consists of information from lines 1-3 on page 7, and lines 20-27 on page 11, of WO 93/13202.

9. The amendatory material, thus, consists of the same material incorporated by reference.

10. I hereby declare that all statements made herein are of my own knowledge true and statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

March 28, 2001
Date

Doreen Yatko Trujillo
Doreen Yatko Trujillo
Registration No. 35,719

WOODCOCK WASHBURN KURTZ
MACKIEWICZ & NORRIS LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100 -Telephone
(215) 568-3439 - Facsimile

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Pizza et al.

Serial No.: 09/819,917

Group No.: Not Yet Assigned

Filing Date: March 28, 2001

Examiner: Not Yet Assigned

For: IMMUNOGENIC DETOXIFIED MUTANTS OF CHOLERA TOXIN

I, Doreen Yatko Trujillo, Registration No. 35,719 certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Box DSD, Assistant Commissioner for Patents, Washington, D.C. 20231.

On October 29, 2001
Doreen Yatko Trujillo
Doreen Yatko Trujillo, Reg. No. 35,719

BOX DSD

Assistant Commissioner for Patents
Washington, D.C. 20231

STATEMENT UNDER 37 C.F.R. §3.73(b)

Chiron S.p.A., a corporation, states that it is:

1. the assignee of the entire right, title, and interest; or
2. an assignee of an undivided part interest

in the patent application/patent identified above by virtue of either:

- A. An assignment from the inventor(s) of the patent application/patent identified above.
 1. The assignment was recorded in the Patent and Trademark Office at Reel 011301, Frame(s) 0630.
 2. The assignment has not yet been recorded. A copy of the assignment is attached.

OR

- B. A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

- i. From: @@ To: @@ The document was recorded in the Patent and Trademark Office at Reel @@, Frame(s) @@, or for which a copy thereof is attached.
- ii. From: @@ To: @@ The document was recorded in the Patent and Trademark Office at Reel @@, Frame(s) @@, or for which a copy thereof is attached.
- iii. From: @@ To: @@ The document was recorded in the Patent and Trademark Office at Reel @@, Frame(s) @@, or for which a copy thereof is attached.

- Additional documents in the chain of title are listed on a supplemental sheet.
 Copies of assignments or other documents in the chain of title are attached.

The undersigned (whose title is supplied below) is empowered to act on behalf of the assignee, Chiron S.p.A.

Date: 14 August 2001



Name: Alisa A. Harbin
Title: Vice President and Associate Chief
Patent Counsel
Corporation: Chiron Corporation

DOCKET NO. CHIR-0312

PATENT

[COMMENT1]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: **Mariagrazia Pizza,
Maria Rita Fontana, Valentina Giannelli and
Rino Rappuoli**

Group Art Unit: Not Yet
Assigned

For: **IMMUNOGENIC DETOXIFIED
MUTANTS OF CHOLERA TOXIN**

Examiner: Not Yet Assigned

DECLARATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name; and

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a

Utility Patent Design Patent

is sought on the invention, whose title appears above, the specification of which:

- is attached hereto.
 was filed on March 28, 2001 as Serial No. 09/819,917.
 said application having been amended on

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to be material to the patentability of this application in accordance with 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a-d) of any **foreign application(s)** for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of any application on which priority is claimed:

Priority	Country	Serial Number	Date Filed
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Claimed
(If X'd)

United Kingdom9513371.6June 30, 1995ItalyMI 91 A 03513December 31, 1991

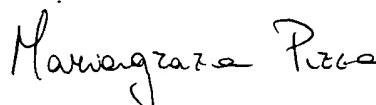
I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to be material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Serial Number	Date Filed	Patented/Pending/Abandoned
<u>08/981,208</u>	<u>December 22, 1997</u>	<u>Pending</u>
<u>08/823,120</u>	<u>March 25, 1997</u>	<u>Now, U.S. Pat. No. 6,149,919</u>
<u>08/256,003</u>	<u>November 11, 1994</u>	<u>Abandoned</u>

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

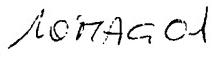
Serial Number	Date Filed
_____	_____
_____	_____

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name: Mariagrazia Pizza	 Signature
Mailing Address: Via Vittorio Emanuele, 33 53100 Siena Italy	Date of Signature: 10/05/01
City/State of Actual Residence: 53100 Siena Italy	Citizenship: Italian

Name: Maria Rita Fontana	 Signature
Mailing Address: Via del Colle, 19 53100 Siena Italy	Date of Signature: 10/05/01
City/State of Actual Residence: 53100 Siena Italy	Citizenship: Italian

Name: Valentina Giannelli	
-------------------------------------	--

Name: Valentina Giannelli	
Mailing Address: Via Corsano Grotti, 26 53010 Ville di Corsano Monteroni d'Arbia (SI) Italy	 
City/State of Actual Residence: Monteroni d'Arbia (SI) Italy	

Name: Rino Rappuoli	 Signature
Mailing Address: Via delle Rocche, 1 Vagliagli 53019 Castelnuovo Berardenga (SI) Italy	
City/State of Actual Residence: 53019 Castelnuovo Berardenga (SI) Italy	Date of Signature: 10/05/01
	Citizenship: Italian

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Pizza et al.**Serial No.: 09/819,917****Group No.: Not Yet Assigned****Filing Date: March 28, 2001****Examiner: Not Yet Assigned****For: IMMUNOGENIC DETOXIFIED MUTANTS OF CHOLERA TOXIN**

I, Doreen Yatko Trujillo, Registration No. 35,719 certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Box DSD, Assistant Commissioner for Patents, Washington, D.C. 20231.

On October 29, 2001
Doreen Yatko Trujillo
Doreen Yatko Trujillo Reg. No. 35,719

BOX DSD

Assistant Commissioner for Patents
Washington, D.C. 20231

POWER OF ATTORNEY

Pursuant to 37 C.F.R. § 1.36, Chiron S.p.A., the Assignee of the above-identified application, hereby appoints the following attorneys and agents to prosecute this application and to transact all business in the Patent and Trademark Office in connection therewith.

Robert P. Blackburn	Registration No. 30,447	Joseph H. Guth	Registration No. 31,261
Alisa A. Harbin	Registration No. 33,895	Charlene A. Launer	Registration No. 33,035
David P. Lentini	Registration No. 33,944	Kimberlin L. Morley	Registration No. 35,391
Lisa E. Alexander	Registration No. 41,576	Anne S. Dollard	Registration No. 43,935

of CHIRON CORPORATION, 4560 Horton Street, Emeryville, CA 94608-2916, and

Richard E. Kurtz	Registration No. 19,263	Lynn B. Morreale	Registration No. 32,842
Dale M. Heist	Registration No. 28,425	Mark DeLuca	Registration No. 33,229
John W. Caldwell	Registration No. 28,937	Joseph Lucci	Registration No. 33,307
Gary H. Levin	Registration No. 28,734	Michael P. Dunnam	Registration No. 32,611
Steven J. Rocci	Registration No. 30,489	Michael D. Stein	Registration No. 34,734
Dianne B. Elderkin	Registration No. 28,598	Albert J. Marcellino	Registration No. 34,664
John P. Donohue, Jr.	Registration No. 29,916	David R. Bailey	Registration No. 35,057
Henrik D. Parker	Registration No. 31,863	Doreen Yatko Trujillo	Registration No. 35,719
Suzanne E. Miller	Registration No. 32,279	Barbara L. Mullin	Registration No. 38,250

Michael P. Straher	Registration No. 38,325	Raymond N. Scott, Jr.	Registration No. P48,666
Kevin M. Flannery	Registration No. 35,871	David L. Marcus	Registration No. 46,897
David A. Cherry	Registration No. 35,099	Christine A. Goddard	Registration No. 46,731
Robert B. Washburn	Registration No. 16,574	Ellen M. Klann	Registration No. 44,836
Norman L. Norris	Registration No. 24,196	Andrew J. Hagerty	Registration No. 44,141
Lynn A. Malinoski	Registration No. 38,788	Emma R. Dailey	Registration No. P48,491
Steven B. Samuels	Registration No. 37,711	Stephen C. Timmins	Registration No. P48,481
Anthony J. Rossi	Registration No. 24,053	Erich M. Falke	Registration No. P49,049
Terence P. Strobaugh	Registration No. 25,460	Jane Smith Inglese	Registration No. P48,444
Michael J. Swope	Registration No. 38,041		
Michael J. Bonella	Registration No. 41,628		
Harold H. Fullmer	Registration No. 42,560		
John E. McGlynn	Registration No. 42,863		
Jonathan M. Waldman	Registration No. 40,861		
Paul K. Legaard	Registration No. 38,534		
Chad Ziegler	Registration No. 44,273		
Gwilym J.O. Attwell	Registration No. 45,449		
David N. Farsiou	Registration No. 44,104		
Steven H. Meyer	Registration No. 37,189		
Paul B. Milcetic	Registration No. 46,261		
Joseph R. Condo	Registration No. 42,431		
Michael K. Jones	Registration No. 41,100		
Frank T. Carroll	Registration No. 42,392		
Mark J. Rosen	Registration No. 39,822		
Mitchell R. Brustein	Registration No. 38,394		
Eric H. Vance	Registration No. 47,151		
Peter M. Ullman	Registration No. 43,963		
Thomas E. Watson	Registration No. 43,243		
Richard B. LeBlanc	Registration No. 39,495		
Joseph D. Rossi	Registration No. 47,038		
Rosaleen P. Morris	Registration No. 47,321		
George J. Awad	Registration No. 46,528		
Steven D. Maslowski	Registration No. 46,905		
S. Maurice Valla	Registration No. 43,966		
Vincent J. Roccia	Registration No. 43,887		
Robin S. Quartin	Registration No. 45,028		
Patrick J. Farley	Registration No. 42,524		
Gregory L. Hillyer	Registration No. 44,154		
Susan C. Murphy	Registration No. 46,221		

of WOODCOCK WASHBURN KURTZ MACKIEWICZ & NORRIS LLP, One Liberty
Place - 46th Floor, Philadelphia, Pennsylvania 19103

Send all future correspondence to:

Alisa A. Harbin, Esq.
CHIRON CORPORATION
Intellectual Property
P.O. Box 8097
Emeryville, CA 94662-8097
Telephone: (510) 923-2708
Facsimile: (510) 655-3542

Direct all telephone calls to:

Doreen Yatko Trujillo, Esq.
WOODCOCK WASHBURN KURTZ
MACKIEWICZ & NORRIS LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone No.: (215) 568-3100
Facsimile No.: (215) 568-3439

- A Statement under 37 C.F.R. §3.73(b) and copies of relevant documents accompany this Power of Attorney.

CHIRON CORPORATION

Date: 14 January 2001

By:

Name: Alisa A. Harbin

Title: Vice President and Associate Chief
Patent Counsel

